

Applicant: Don Fishbein
Serial No.: 10/799,197
Filed: March 12, 2004
Page 5

REMARKS

Claims 30-45 are pending in the subject application. By this amendment applicant has added new claims 46 and 47. Applicant maintains that the amendment to the claims raises no issue of new matter. Upon entry of this Amendment claims 30-46 will be pending. Support for new claim 46 may be found in the specification at, inter alia, page 8, lines 29 to 32; page 9, lines 12-14. Support for new claim 47 may be found in the specification at, inter alia, page 20, lines 10 and 11; Figs. 7 and 8; and page 19, line 31.

Double Patenting

The Examiner provisionally rejected claims 30-45 under non-statutory obviousness-type double patenting over co-pending U.S. Serial No. 10/799,264. The Examiner indicated that a timely filed Terminal Disclaimer in compliance with 37 C.F.R. §§1.321(c) or 1.321(d) may be used to overcome a provisional rejection.

In response, applicant directs the Examiner's attention to the Terminal Disclaimer filed on May 16, 2006 in connection with the above-identified application which disclaimed over co-pending U.S. serial No. 10/799,264 (see PAIR entry dated 5-19-06).

Applicant: Don Fishbein
Serial No.: 10/799,197
Filed: March 12, 2004
Page 6

Claims Rejected Under 35 U.S.C. §103(a)

Claims 30-40 and 42-45

In the March 23, 2007 Office Action, the Examiner rejected claims 30-40 and 42-45 under 35 U.S.C. §103(a) as allegedly obvious over Berger (U.S. Patent No. 6,090,799) in view of Schafer (U.S. Patent No. 4,456,596). The Examiner stated, inter alia, that Berger teaches that "[a]nabolic steroids, as a class, are known to stimulate appetite", and that oxandrolone "increases protein synthesis". The Examiner also stated that Berger teaches that "[i]mproved nutrition is important to individuals with AIDS who have experienced loss of lean body mass". The Examiner further stated that Berger "does not teach the use of anabolic steroids in the treatment of burns." The Examiner asserted that Schafer teaches the use of topically or systemically applied drugs, such as anabolic steroids, for healing processes of tissue lesions such as burns. The Examiner stated that one of ordinary skill in the art would be motivated to combine the teachings of Berger and Schafer because the patents "teach overlapping subject matter, namely treatment using anabolic steroids" and alleged that applicant's invention as claimed is obvious over the combination of references.

In response, applicant respectfully traverses the Examiner's rejection.

Applicant: Don Fishbein
Serial No.: 10/799,197
Filed: March 12, 2004
Page 7

Applicant's invention as claimed not obvious

In light of the points presented hereinbelow, applicant maintains that it is not obvious to one of ordinary skill in the art that oxandrolone treatment of post-burn catabolic weight loss is somehow rendered obvious by Berger's disclosure of a treatment of a *different* pathology with oxandrolone, and this is not cured by combination with Schafer, a reference that teaches topical application of different steroid to topically treat burn wounds, not weight loss resulting from post-burn catabolism. In addition, there is no reasonable expectation of success of combining selected elements of two divergent therapies for two dissimilar pathologies to somehow arrive at applicant's claimed method. Moreover, even if the references are combined as suggested by the Examiner, they still do not teach or suggest all the elements of applicant's claimed method. Furthermore, applicant's method as claimed produces unexpected results not suggested by the prior art cited.

1. Different populations, having different weight-loss etiologies

Applicant initially notes that Berger (patients suffering HIV-associated weight loss) and Schafer (burn victims) each teach different patient populations from the patient population of applicant's invention as claimed (patients suffering from weight loss induced by post-burn catabolism). The different etiology of weight loss set forth in Berger (HIV-associated myopathy; see col. 1, lines 15-18 and 30-32) compared to the present application (burn injury-induced; see page 1, lines 30-33 and

Applicant: Don Fishbein
Serial No.: 10/799,197
Filed: March 12, 2004
Page 8

page 2, lines 18-20) is not germane to, and does not suggest or teach, even in combination with the teachings of Schafer (which does not discuss weight loss), the invention as claimed. In short, Berger in combination with Schafer neither discuss the subject population recited in the claims nor the recited weight loss to be treated. Consequently, one of ordinary skill in the art would not have an expectation of success in treating post-burn catabolism-induced weight loss based on the cited art, which neither describes nor suggests the population or pathology as recited in applicant's claims. Applicant maintains that for an obviousness rejection to be proper there must be at least a reasonable expectation of success, but that the cited references provide no suggestion of the claimed treatment or a reasonable expectation of its success.

2. Different Use of Steroids

Applicant notes that the Examiner stated in the March 23, 2007 Office Action that Berger does not teach use of oxandrolone for the treatment of burns but that Schafer teaches the use of topically or systemically applied drugs, such as anabolic steroids, for healing processes of tissue lesions, such as burns. Applicant takes this opportunity to clarify the facts; Schafer does not state that anabolic steroids are used systemically to treat burns. To quote, Schafer states: "The use of topically or systemically applied drugs for accelerated healing processes of physically, chemically or physiologically induced tissue lesion, such as burns, surgery or ulcers, is described in the medicinal literature." (see col. 1, lines 10-

Applicant: Don Fishbein
Serial No.: 10/799,197
Filed: March 12, 2004
Page 9

19). Schafer then goes on to state that "[f]or example, there are reports on anabolic steroids, vitamin A, vitamin K, zinc compounds, silver compounds or serum factors, e.g. factor XIII in blood coagulation, or high molecular compounds such as collagen or cartilage which all accelerate the healing process of tissue injuries." In short, Schafer nowhere actually states that anabolic steroids are given systemically. Schafer does, however, specifically suggest that steroids are used *topically* (see col. 8, line 64 to col. 9, line 15 and col. 9 lines 23 to 33 where the glycosteroid isolated by Schafer is applied to burns in the form of an ointment or gel). Thus Schafer, taken in combination with Berger, do not teach or suggest systemic administration of oxandrolone (e.g. orally or injected as recited in applicant's claim 46) to treat weight loss resulting from post-burn catabolism.

3. Diverse technical fields

Applicant further notes that the Examiner has characterized Berger and Schafer as combinable based on their "overlapping subject matter". However, the professed technical field of Schafer is "materials in mammalian tissues or fluids which accelerate wound healing", (see col. 1, lines 5-8). In contrast, Berger states that the technical field of the invention is "use of oxandrolone to attenuate myopathy and muscle weakness/wasting associated with infection by human immune deficiency virus-Type 1". Accordingly, it is not clear that a one of ordinary skill in the art would find the "subject matter" to be overlapping, merely that both documents discuss

Applicant: Don Fishbein
Serial No.: 10/799,197
Filed: March 12, 2004
Page 10

anabolic steroids. Moreover, the technical fields of the papers being divergent would not lead one to combine the disclosures of the documents and would not give rise to a reasonable expectation of success.

4. Unexpected results

Applicant further notes that there is no *a priori* reason to conclude that a weight loss induced by AIDS can be treated in the same way as weight loss resulting from post-burn catabolism. Indeed while the Examiner states that Berger teaches that "anabolic steroids are known to stimulate appetite" applicant notes that the present specification teaches that even with the same calorific intake, a dramatically increased weight gain is seen in patients treated with oxandrolone. If weight gain was due to increased appetite (and consequent increased calorific intake) one would not expect to see up to double the weight gain (see page 20, lines 10 and 11; and Figs. 7 and 8, group I compared to group II) in subjects treated with oxandrolone compared to subjects not administered oxandrolone but having almost identical caloric intake (of which the protein intake was "identical", see page 19, line 31). Thus the present application discloses an unexpectedly high weight gain which cannot be explained by increased appetite per se. Berger in combination with Schafer does not anywhere suggest such an outcome.

Claims 30 and 41

The Examiner also rejected claims 30 and 41 under 35 U.S.C. §103(a) as allegedly obvious over Berger, as cited, in view of

Applicant: Don Fishbein
Serial No.: 10/799,197
Filed: March 12, 2004
Page 11

Schafer, as cited, and in further view of Labrie et al. (U.S. Patent No. 5,434,146). The Examiner indicated that the teachings of Berger and Schafer are as indicated above, but that Berger does not teach the administration of oxandrolone in a sustained release formulation. The Examiner further asserted that Labrie et al. teach the administration of oxandrolone in a sustained release formulation. The Examiner alleged that in view of this it would have been prima facie obvious to one of ordinary skill in the art that the administration of an effective amount of oxandrolone in a sustained release formulation would be effective for promoting weight gain after weight loss resulting from post-burn catabolism.

Applicant notes that, as set forth hereinabove, there is no teaching of the method of claim 30 in the combination of Berger and Schafer, and Labrie et al. does not cure this deficiency, nor does the Examiner suggest that it does. In fact Labrie et al. does not teach weight gain therapies or subjects that have experienced a burn, but instead teaches treatment and prevention of estrogen-related diseases (see Abstract and Summary of Invention). The Examiner does assert that the Labrie et al. discloses administration of oxandrolone in a sustained release formulation. To the extent that Labrie et al. may teach a sustained release composition, it still does not teach a method of administration of oxandrolone to a patient for treating weight loss resulting from post-burn catabolism, nor does it cure the other deficiencies of the combination of Berger and

Applicant: Don Fishbein
Serial No.: 10/799,197
Filed: March 12, 2004
Page 12

Schafer. Applicant maintains that the cited combined references do not teach or make obvious applicant's invention as claimed.

Thus, applicant maintains that claims 30-47 as amended are not obvious over the combination of cited references. Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw this ground of rejection.